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voltage 45 kV, intensity 40 mA,

mounting  $\theta$ - $\theta$ ,

nickel (Kβ) filter,

incident-beam and diffracted-beam Soller slit: 0.04 rad,

fixed angle of divergence slits: 1/8°,

mask: 10 mm, antiscatter slit: 1/4°

measurement mode: continuous from  $3^{\circ}$  to  $30^{\circ}$ , in increments of  $0.017^{\circ}$ ,

ments of 0.017,

measurement time per step: 19.7 s,

total time: 4 min 32 s, measurement speed: 0.108°/s,

measurement temperature: ambient.

## EXAMPLE 1

## β-Crystalline Form of Ivabradine Hydrochloride

720~ml of purified water are preheated to  $50^{\circ}$  C., and then 250~g of ivabradine hydrochloride obtained according to the 20~process described in the patent specification EP 0.534~859 are added in portions, with stirring, and the mixture is heated at  $74^{\circ}$  C. until dissolution is complete. The resulting clear solution is heated for 2 more hours at  $74^{\circ}$  C. and is then progressively cooled, first to  $40^{\circ}$  C., and then to ambient temperature. 25~ The solution is subsequently stored at ambient temperature for 2 days, and then the solid suspension is spread out in a thin layer on a crystallisation plate. The excess water is driven off under a gentle current of nitrogen.

The water content of the resulting product, determined by 30 coulometry, is 12.4%, which corresponds to a tetrahydrate.

X-ray Powder Diffraction Diagram:

The X-ray powder diffraction profile (diffraction angles) of the  $\beta$ -form of ivabradine hydrochloride is given by the significant rays collated in the following table:

Ray no.	Angle 2 theta (degrees)	Height (counts)	Area (counts × degrees)	FWHM (degrees)	Interplanar distance (Å)
1	6.8	130	86	0.6691	13.019
2	9.2	6141	507	0.0836	9.613
2 3	9.7	882	58	0.0669	9.083
4	10.0	875	72	0.0836	8.837
5	11.9	190	19	0.1004	7.433
6	12.2	500	58	0.1171	7.236
7	13.2	224	30	0.1338	6.694
8	13.8	633	52	0.0836	6.419
9	14.3	466	54	0.1171	6.209
10	14.8	926	76	0.0836	5.977
11	15.0	716	94	0.1338	5.887
12	15.7	531	79	0.1506	5.636
13	16.1	121	16	0.1338	5.502
14	16.9	1354	223	0.1673	5.254
15	18.4	5672	562	0.1004	4.824
16	18.8	1328	131	0.1004	4.716
17	19.7	1617	347	0.2175	4.508
18	20.4	296	34	0.1171	4.341
19	20.7	767	51	0.0669	4.286
20	21.3	1419	211	0.1506	4.178
21	21.6	2458	243	0.1004	4.114
22	22.6	1737	258	0.1506	3.937
23	23.0	1467	73	0.0502	3.865
24	23.7	486	128	0.2676	3.751
25	23.9	504	50	0.1004	3.718
26	25.3	4606	304	0.0669	3.513
27	25.7	791	91	0.1171	3.464
28	26.2	458	91	0.2007	3.406
29	26.6	221	44	0.2007	3.352
30	27.4	706	151	0.2175	3.251
31	27.7	208	27	0.1338	3.215

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Ray no.	Angle 2 theta (degrees)	Height (counts)	Area (counts × degrees)	FWHM (degrees)	Interplanar distance (Å)
32	28.1	483	40	0.0836	3.176
33	28.8	242	24	0.1004	3.096
34	29.3	450	74	0.1673	3.049

## **EXAMPLE 2**

## Pharmaceutical Composition

Formula for the preparation of 1000 tablets each containing 5 mg of ivabradine base:

Compound of Example 1	5.39 g	
Maize starch	20 g	
Anhydrous colloidal silica	0.2 g	
Mannitol	63.91 g	
PVP	10 g	
Magnesium stearate	0.5 g	

The invention claimed is:

1. A  $\beta$ -Crystalline form of ivabradine hydrochloride of formula (I):

$$\begin{array}{c} \text{CH}_3\text{O} \\ \text{CH}_3\text{O} \\ \text{O} \\ \text{O} \\ \text{O} \end{array} \quad \begin{array}{c} \text{CH}_3 \\ \text{O} \\ \text{O} \\ \text{O} \\ \text{O} \\ \text{O} \end{array} \quad \begin{array}{c} \text{CH}_3 \\ \text{O} \\ \text{O$$

having a powder X-ray diffraction diagram exhibiting peaks at 9.2, 18.4, 19.7, 21.6 and 25.3 deg 2 theta.

**2**. A  $\beta$ -Crystalline form of ivabradine hydrochloride of formula (I):

55 having a powder X-ray diffraction diagram exhibiting peaks at 9.2, 9.7, 10.0 and 14.8 deg 2 theta.

3. A solid pharmaceutical composition comprising as active ingredient the  $\beta$ -crystalline form of ivabradine hydrochloride of claim 1, in combination with one or more pharmaceutically acceptable, inert, non-toxic carriers.

4. A method for treating a condition selected from angina pectoris, myocardial infarct, and heart failure, such method comprising administering to a human, a therapeutically effective amount of the  $\beta$ -crystalline form of ivabradine hydrochloride of claim 1.

5. A solid pharmaceutical composition comprising as active ingredient the  $\beta$ -crystalline form of ivabradine hydro-